

K024282

MAR 21 2003

INOVATIV, LLC.

1155 Twin Hills Drive
Jefferson, OR. 97352
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510 (K) Summary

Submitter Name:	Inovativ, LLC.
Submitter Address:	1155 Twin Hills Drive Jefferson, OR 97352
Submitter Telephone:	(503)585-4362
Submitter Facsimile:	(503)585-1188
Contact Person:	Bob Bowers Chief Operating Officer
Date Summary Prepared:	November 18, 2002

Inovativ Acrylic
Original Premarket 510(K) Notification

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR.807.92.

9.1 SUBMITTER INFORMATION

- | | |
|---------------------------|--|
| a. Company Name: | Inovativ, LLC. |
| b. Company Address: | 1155 Twin Hills Drive
Jefferson, OR 97352 |
| c. Company Telephone: | (503)585-4362 |
| Company Facsimile: | (503)585-1188 |
| d. Contact Person: | Bob Bowers
Chief Operating Officer |
| e. Date Summary Prepared: | November 18, 2002 |

9.2 DEVICE IDENTIFICATION

- | | |
|----------------------------|---|
| a. Trade/Proprietary Name: | Acrylic |
| b. Classification Name: | Temporary Crown and Bridge Resin
21 CFR 872.3770 |

9.3 IDENTIFICATION OF PREDICATE DEVICES

The Acrylic material is a thermoplastic resin used to prefabricate partial denture clasps, temporary crowns and bridges. This material is substantially equivalent to the Health-Dent International, Inc. "Dent-Temp Acrylic". This material is commercially available in the United States.

9.4 DEVICE DESCRIPTION

The Acrylic material is a thermoplastic resin that is used to fabricate dental prostheses. The resin is used in an injection molding or pressing device to fabricate the prostheses.

9.5 SUBSTANTIAL EQUIVALENCE

The Acrylic thermoplastic Acrylic resin is substantially equivalent to the Health-Dent International, Inc. "Dent-Temp Acrylic" Acrylic resin. The fundamental characteristics are similar: the Acrylic thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

9.6 INDICATIONS FOR USE

The Acrylic is intended for the fabrication of temporary dental prostheses like partial denture clasps, temporary crowns, and bridges using the Inovativ, LLC Acrylic resin.

9.7 TECHNOLOGICAL CHARACTERISTICS

Chemical composition and properties of the Acrylic is provided within this submission. Both the Acrylic and the predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Mr. Robert Bowers
Chief Operating Officer
Inovativ, LLC
1155 Twin Hills Drive
Jefferson, Oregon 97352

Re: K024282
Trade/Device Name: Acrylic
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: November 18, 2002
Received: December 23, 2002

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

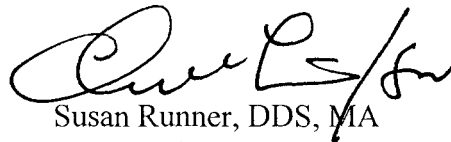
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by a stylized flourish.

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Inovativ Acrylic
Original Premarket 510(K) Notification

SECTION 8. 510(K) STATEMENT OF INDICATIONS FOR USE

The 501(K) statement of indications for use for this device is being submitted in accordance with the requirements of 21 CFR 807.87.

8.1 STATEMENT OF INDICATIONS FOR USE.

Indications for Use

510(k) Number K024282

Device Name Acrylic

Indications for use:

The Acrylic is intended for the fabrication of temporary dental prostheses like temporary crowns and bridges, flippers, orthodontic retainers, and occlusal guards using the Inovativ, LLC Acrylic resin.

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Prescription Use X
(Per 21 CFR 801.109)

OR

Over the counter _____

(Optional Format 1-2-96)

8-1

Rein Muey for ASR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024282